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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,546	06/04/2007	Romi Barat Singh	RLL-499US	7158

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Ranbaxy Inc.
Intellectual Property Department
600 College Road East
PRINCETON, NJ 08540

EXAMINER	
MATTISON, LORI K	
ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
05/14/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general.ip.mailbox@ranbaxy.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,546	SINGH ET AL.	
	Examiner	Art Unit	
	LORI K. MATTISON	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-12* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's arguments, filed 04/17/2012, are acknowledged and have been fully considered.

2. Claims 1-12 are pending.

Claims 13-18 are cancelled.

No claims have been amended.

Claims 1-12 have been examined on the merits.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Maintained Grounds of Rejection

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over AMIDON 2004 in view of ARZENO 1997, DRUG MONITOR 2002, HANCOCK 1997, STANIFORTH 2003, and VALENTINE 1995 (as evidenced by SHARMA 2007 and the definition of Crystallization (2008)) for the reasons of record in Paper No. 20110811, and as follows.

Response to Arguments

Applicant argues that AMIDON teaches about 250 active pharmaceutical agents for use in his composition but does not teach amorphous valganciclovir hydrochloride (Reply, pg. 2).

Applicant's argument is not persuasive. AMIDON teaches valganciclovir hydrochloride as one of the pharmaceutical agents which may be used in his tablet (¶ 34).

Applicant argues the process of AMIDON creates a dosage form with sustained release properties whereas Applicant's process creates a dosage form with immediate release dosing (Reply, pg.2).

Applicant's argument has been considered but is not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., immediate release dosing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the prior art does not recognize any need for formulating the amorphous form of valganciclovir and does not provide the skilled artisan with the suggestion or motivation to develop a dry process for the preparation of stable solid dosage forms of valganciclovir. (Reply, pg. 3, 5, and 6). Applicant also argues that DRUG MONITOR does not say that there was a problem with the bioavailability of valganciclovir and merely states the bioavailability effects of the drug (Reply, pg. 3).

Applicant arguments have been considered but are not persuasive. With regard to the motivation for the development of a dry process, the reason or motivation to modify the

reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.(See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

With regard to Applicant's allegation that DRUG MONITOR does not teach a problem with the bioavailability of the drug but merely teaches that there is a food effect, DRUG MONITOR explicitly states that a "High fat food significantly increases the bioavailability and peak serum level" of valganciclovir (Drug Monitor-pg. 2). Thus DRUG MONITOR teaches that in absence of high fat food, the bioavailability of valganciclovir is not as high than if it were administered with a high fat food, which is a problem well known in the art.

With regard to the suggestion and motivation to utilize the amorphous valganciclovir taught by ARENZO in AMIDON's process-of-making, the skilled artisan would have been motivated to select amorphous valganciclovir for use in the invention because it is well known in the art that orally delivered valganciclovir hydrochloride has a bioavailability problem, and artisans in the field were endeavoring to find ways to improve the bioavailability of the drug. In addition, amorphous pharmaceutical drugs may have enhanced dissolution and bioavailability as taught by the combined teachings of DRUG MONITOR and HANCOCK.

Applicant argues that ARENZO does not teach amorphous crystalline valganciclovir (Reply, pg. 4).

Applicant's argument is not persuasive for the reasons of record found in the rejection of Paper No. 20110128 and the "Response to Arguments" in Paper No. 20110811. **The issue remains whether the valganciclovir taught by ARENZO is amorphous or crystalline.** While

not explicitly stated that the method taught by ARZENO embraces amorphous as well as crystalline valganciclovir, it is observed that Example 6 of ARZENO discloses the process of forming valganciclovir hydrochloride by attaching the hydrochloride ion to the N-CBZ-monovalinate-monobenzyl-ganciclovir through use of a palladium hydroxide catalyst (page 48, last ¶). ARZENO teaches the reaction is permitted to go to completion, indicating that valganciclovir hydrochloride was formed, and mixture was filtered and stripped to a low volume (page 48, last ¶). Water was added and the solution was stripped again to remove the methanol (page 48, last ¶). Isopropanol was added (thus creating a water and isopropanol mixture) was added and this initiated crystallization (page 48, last ¶). As evidenced by the *Encyclopedia Britannica*, crystallization is a purification technique in which solids precipitate from a *saturated* solution (page 2, ¶s 1-3). This is distinguished from precipitation which is a process in which an *insolubl*e compound is formed by a chemical reaction (page 2, ¶ 4). Thus, ARZENO teaches that a solid was formed (page 48, last ¶). More isopropyl was added and the mixture was stirred, cooled, filtered and dried (page 49, ¶ 1). Similarly, as evidenced by SHARMA, amorphous valganciclovir is formed by reacting N-benzyloxycarbonyl-L-valinate ester of ganciclovir with hydrochloric acid, dissolving the residue in an organic solvent (which may be isopropanol) and removing the solvent to achieve amorphous valganciclovir hydrochloride (Sharma, ¶s 20 and 21). Therefore, the examiner reasonably concludes that ARZENO teaches amorphous valganciclovir since the processes have the same steps and reagents unless Applicant can provide evidence to the contrary.

Conclusion

5. No claims are allowed.

6. This is a RCE of applicant's earlier Application No. 10/598546. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI K. MATTISON whose telephone number is (571)270-5866. The examiner can normally be reached on 8am-6pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DAVID BLANCHARD can be reached on (571)272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LORI K MATTISON/
Examiner, Art Unit 1619
May 6, 2012

/ROBERT C. HAYES/
Primary Examiner, Art Unit 1649